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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/057,116
Filing Date: January 24, 2002
Appellant(s): WHITEHURST ET AL.

Steven L. Nichols
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 8, 2006 appealing from the Office action mailed July 14, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

A substantially correct copy of appealed claim 15 appears on page 31 of the Appendix to the appellant's brief. The minor errors are as follows: on line 5, the term "peripherial" should be replaced by the word "peripheral" as per the amendment after Final received December 8, 2006 and approved for entry by the examiner.

(8) Evidence Relied Upon

WO 98/37926	Schulman et al.	9-1998
6480745	Nelson et al.	11-2002

Novak et al., "Outcome Following Implantation of a Peripheral Nerve Stimulator in Patients with Chronic Nerve Pain," Plastic and Reconstructive Surgery, Washington U. School of Medicine, May 2000, pp. 1967-1972.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-6, 8, 15, 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al. (WO 98/37926) in view of Novak et al. (the article entitled: "Outcome Following Implantation of a Peripheral Nerve Stimulator in Patients with Chronic Nerve Pain").

Regarding claim 4, Schulman et al. disclose providing at least one leadless stimulator (100) having at least two electrodes (112a and 112b); implanting the at least one stimulator adjacent to at least one nerve (see page 3, lines 9-14), at least in part responsible for sensations in a region experiencing pain (note page 6, lines 10-13); generating stimulation pulses in accordance with stimulation parameters (page 8, line 31- page 9, line 2); delivering the stimulation pulses to nerves adjacent to the at least one stimulator (see page 12, lines 5-9), wherein the stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve (see page 12, lines 2-5).

Although Schulman et al. do not explicitly discuss a method for treating *chronic* pain, Schulman et al. teach that the device may be used to treat pain in general (see page 6, lines 10-16). It is further taught that a rechargeable battery may be employed in those applications requiring longer treatment times due to the recurring nature of the ailment (note for example page 8, lines 8-23 and page 20, line 20- page 21, line 6). Novak et al. further teach that an identified patient with chronic pain can be successfully treated with a peripheral nerve stimulator (see the last paragraphs on pages 1969 and 1971). Given the fact that one of the intended uses of the Schulman et al. device is to treat pain via nerve stimulation, and given the teaching that the implant may be powered indefinitely from an external power source depending on the particular application at

hand, with the treatment of chronic pain by peripheral nerve stimulators known, those of ordinary skill in the art presented with a patient experiencing chronic pain, would have seen the obviousness of utilizing the method of Schulman et al. to block chronic pain and provide a measure of relief to the patient.

Regarding the limitation concerning peripheral nerves, because the device of Schulman et al. with its relatively small size is capable of being placed in virtually any region of the body that may require nerve stimulation treatment, and because Schulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation – especially in view of the teachings of Novak et al.. The type of pain to be treated and the physiology of the nervous system would naturally dictate where the most effective application site resides.

Regarding limitations directed to specific nerves or chronic pain locations, as reasoned above, because the device of Schulman et al. with its relatively small size is capable of being placed in virtually any region of the body that may require nerve stimulation treatment, and because Schulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation.

Regarding the step of identifying a patient experiencing sensations of chronic pain, it is axiomatic that Schulman et al. must identify a patient experiencing pain if they intend to use the device to treat pain as disclosed. Novak et al. further teach that successful pain relief depends upon accurate patient selection.

Regarding claims 5 and 6, see page 22, lines 7-17 of Schulman et al..

Regarding claim 8, all of the above comments made in support of the rejection of similarly worded limitations apply here as well.

Regarding claim 15, comments paralleling those made in the rejection of claim 4 apply here as well. Regarding limitations directed to details of the sensor, note page 14, lines 9-28 of Schulman et al..

Regarding claim 16, Schulman et al. show in Fig. 2 a diagram of the stimulator containing a sensor 188 coupled to the stimulation electrodes.

Regarding claim 20, see Fig. 3A.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al. (WO 98/37926) in view of Novak et al. (the article entitled: "Outcome Following Implantation of a Peripheral Nerve Stimulator in Patients with Chronic Nerve Pain") as applied to claims 4-6, 8, 15, 16 and 20 above, and further in view of Nelson et al. (Pat. No. 6,480,745).

Schulman et al. and Novak et al. do not discuss the transmission of stimulation parameters to an external device. Nelson et al., however, disclose a common and well-known method applicable to nerve stimulators that allows for such transmission and monitoring (note for example col. 2, lines 39-67, etc.). The performance of such a method has the explicit advantage of allowing continuous monitoring and immediate programming updates by remotely located medical personnel. Artisans of ordinary skill in the art desirous of such benefits would have therefore seen the obviousness of incorporating the steps of Nelson et al. into the method defined by Schulman et al. and Novak et al..

(10) Response to Argument

With regards to claim 4, the appellant argues that the cited combination of prior art references fails to teach or suggest a method of treating a patient with chronic pain by delivering stimulation pulses to at least one of an intercostal nerve, an intercostal nerve branch, a greater occipital nerve, a lesser occipital nerve, and a third occipital nerve. The appellant further asserts that the Office Action (Action of July 14, 2006) is unable to cite and fails to address any portion of the prior art that actually suggests or teaches the claimed method including delivering stimulation pulses to the specific target nerves listed.

The examiner counters that the Office Action did indeed address the issue of targeting specific nerves as repeated below.

> *Regarding the limitation concerning peripheral nerves*, because the device of Schulman et al. with its relatively small size is capable of being placed in virtually any region of the body that may require nerve stimulation treatment, and because Schulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation –especially in view of the teachings of Novak et al.. The type of pain to be treated and the physiology

> of the nervous system would naturally dictate where the most effective application site resides.
>
> *Regarding limitations directed to specific* nerves *or chronic pain locations*, as reasoned above, because the device of Schulman et al. with its relatively small size is capable of being placed in virtually any region of the body that may require nerve stimulation treatment, and because Schulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation.

Further elaboration can be found in the section of the Final Rejection entitled, "Response to Arguments."

MPEP § 2142 states:

> To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly *or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references* [emphasis added]." Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

Schulman et al. disclose a microstimulator configured explicitly to be implanted beneath a patient's skin wherein the stimulator device is "...useful in a wide variety of applications to stimulate nerves and associated neural pathways, e.g., to decrease or relieve pain..." (page 6, lines 1-13). Schulman et al. do not explicitly discuss intercostal and occipital nerves because they clearly do not wish to limit their invention to any one particular nerve or neural pathway as the intent of the device is to permit a wide variety of applications and treatments to be realized.

Novak et al. was cited as a secondary reference by the examiner because it specifically teaches that patients suffering from chronic pain can benefit from peripheral nerve stimulation (e.g., see the "Discussion" and "Conclusions" sections on pages 1969 and 1971 respectively) by application of stimulation according to the "gate control" theory (note page 1967, col. 2, lines 8-15 of Novak et al. and par. 0046 of the present invention's specification). Novak et al. further list various peripheral nerves involved in the study (see Table I on page 1970) including radial, ulnar and median nerves –all of which the appellant discloses to be suitable examples of the types of nerves applicable to the present invention (see pars. 0043 and 0044), and all of which were previously claimed (see originally filed claim 4 which grouped together a large variety of peripheral

nerves). The examiner can find nothing in the present invention's disclosure that distinguishes intercostal and occipital nerves from any of the other plethora of suitable peripheral nerves discussed. The appellant has not disclosed any advantage or unexpected result associated with the stimulation of intercostal/occipital nerves over the stimulation of any other peripheral nerves. The appellant has not disclosed any particular challenging problems encountered by prior artisans in the stimulation of intercostal/occipital nerves, and concomitantly has not proposed any solution to any art-recognized problem in the stimulation of such nerves.

The appellant further argues on page 10 of the Appeal Brief that the Final Rejection:

> ...appears to take the position that because the prior art teaches stimulating certain nerves to treat non-chronic pain, it would be obvious to stimulate any other nerve site to treat chronic pain. (Action of 7/14/06, p. 5). This is clearly reading far too much into the prior art. One of ordinary skill in the art, e.g., a physician, would never make such a leap in reasoning.

It is unclear how the appellant can possibly leap to the conclusion that the Final Rejection took the position that the treatment of *non-chronic* pain can be applied to the treatment of chronic pain, when the very gist of the applied Novak et al. reference is drawn to the treatment of *chronic* pain as further elaborated by the title: "Outcome following Implantation of a Peripheral Nerve Stimulator in Patients with *Chronic* [emphasis added] Nerve Pain." The examiner asserts that the party clearly reading "...far too much into the prior art..." is not the examiner, but the appellant. There is nothing in either prior art reference that precludes chronic pain treatment or that limits treatment to only non-chronic situations or specific peripheral nerves.

The appellant then argues that while the teachings of the prior art can be extended as they have done, such extension requires careful experimentation and discovery (page 10). The appellant, however, offers no evidence of record to support this assertion. The examiner also wishes to make the point that "careful experimentation" does not equate to "undue experimentation." It is assumed and hoped that most competent medical artisans would practice careful experimentation when developing their invention. As stated in the Final Rejection, given the disclosures of

Schulman et al. and Novak et al., one of ordinary skill in the art would reasonably expect the procedure to be successful on peripheral nerves in general, with mere routine experimentation required to determine the list of susceptible nerves and candidate patients.

The appellant additionally argues on page 11 of the Brief that the Office Action's stand that it would have been obvious to implant the device near a peripheral nerve if the nerve required stimulation, illustrates a "...leap in reasoning... ." The appellant then poses the question, "How does one determine 'if the peripheral nerve requires stimulation?' " The answer is simple –perform a routine medical examination. The appellant's question is akin to asking a physician how they would know where to place a bandage to treat a wound. The role of the nervous system in transmitting the sensation of pain is well-established. As evidenced by Novak et al., the appellant is not the first to discover that peripheral nerves can be injured or otherwise damaged, resulting in the experience of chronic pain. Novak et al., in fact, explicitly discuss well-established screening and interviewing procedures (see the text abridging pages 1970 and 1971) for evaluating the patient's condition. It is unclear what kind of a "leap in reasoning" would be required for a competent physician to properly diagnose a patient that may have suffered peripheral nerve damage due to injury. If a special technique supposedly unknown by medical practitioners for identifying damaged nerves or otherwise pinpointing the cause of chronic pain is necessary to practice the invention, the appellant has not divulged this identification procedure, raising the question of inadequate disclosure under 35 U.S.C. §112; 1st paragraph.

The appellant goes on to demand that the examiner cite prior art to support the allegation that one of ordinary skill in the art, based on prior art teachings, would obviously modify Schulman and Novak to deliver stimulation pulses to the nerve sites claimed by the appellant. Once again the examiner refers to section § 2142 of the MPEP as cited above, where the implied teachings of the references and logical reasoning may be used to support a case of *prima facie* obviousness. The examiner did not take Official Notice and is under no obligation to provide a reference identically disclosing in explicit, word-for-word terms, the appellant's invention. The examiner

asserts that a reasonable person given the teachings of Schulman et al. and Novak et al. and the logical reasoning proffered by the examiner could only come to the conclusion that a *prima facie* case of obviousness has been established. The burden now shifts to the appellant to provide credible evidence to refute this finding.

The appellant's arguments concerning claim 8 substantially mimic the arguments already presented above (i.e., the appellant alleges that the limitations regarding specific lower limb chronic pain locations have not been addressed to their satisfaction and that the Office Action chooses to "...simply overlook some of the features recited..."). The same evidence, teachings and logical reasoning presented in the rejection of claim 4 by the examiner apply here as well. The examiner further wishes to direct the Board's attention to the second column on page 1971 of the Novak et al. reference:

> evaluated 4 to 29 months after surgery. Eleven patients reported complete pain relief with stimulation, and four reported poor relief. Nashold et al.[12] reported results observed in 35 patients (19 with upper-extremity nerve stimulators and 16 with lower-extremity nerve stimulators). Pain relief as defined by the authors was at least 90 percent relief over the preoperative pain level, increased physical activity, and no use of pain medication. Ten patients with an upper-extremity stimulator and five with a lower-extremity stimulator reported pain relief. Picaza[13] reported results observed in 23 patients who underwent implantation of a peripheral nerve stimulator. The majority of patients had pain originating from the lumbar spine with radiation to the lower extremities. Twenty patients reported pain relief, improvement in social activities, and decreased use of pain medication.

The examiner suffices to say that the term "lower extremities" would --to a reasonably competent person in the medical arts-- suggest treatment of the lower limbs.

Regarding the rejection of claim 15, the appellant states on page 14 of the Brief:

> In Contrast, neither Schulman nor Novak teach or suggest the claimed method for treating chronic pain, which includes "at least one of chronic neuropathic pain, failed back surgery syndrome, arachnoiditis, occipital neuralgia, peripherial [sic] pelvic pain, cardiac pain and back pain." These maladies are not even mentioned by Schulman or Novak.

The examiner responds that the appellant appears to be oblivious to the disclosure of Novak et al. and quotes the following section found on page 1969:

> Successful pain relief with use of a peripheral nerve stimulator depends on accurate patient selection. Most patients referred for consideration of nerve stimulator implantation have had pain for many years and have undergone numerous unsuccessful operations to eliminate the pain. It is often difficult to obtain an accurate history and a good subjective description of the patient's pain. We use a pain evaluation questionnaire based on the McGill Pain Questionnaire and the Hendler 10-Minute Screening Test for Chronic Back Pain Patients.[20-22] Our questionnaire includes a

A reference may be relied upon for all that it would have reasonably suggested to one of ordinary skill in the art. Clearly the teachings of Novak et al. would have suggested application of the invention to the treatment of chronic back pain, failed back surgery syndrome, lumbar pain, etc.

Regarding claim 27, the appellant asserts that the Nelson et al. reference appears only to teach that patient physiological data detected by the IMD will be transmitted for purposes of analysis and quotes several paragraphs from the reference in an attempt to support this conclusion.

The examiner responds by quoting from the same section of Nelson et al. that actually refutes such an assertion. Nelson et al. teaches in col. 2:

> has typically only begun. The IMD usually cannot be merely implanted and forgotten, but must be monitored for optimal results, and may require occasional adjustment of certain parameters or settings, or even replacement, in response to or in anticipation of changes in patient condition or other environmental factors, or based on factors internal to the device. IMDs may also contain logic devices such as digital controllers, which may need to undergo firmware or software upgrades or modifications. In addition, information about the IMD may be gathered for treatment or research purposes. For example, many IMDs are capable of storing certain state information or other data regarding their operation internally in addition to physiological data.

Contrary to the appellant's assertion, Nelson et al. disclose that information *in addition to physiological data* may be stored and gathered for transmission to a remote information network. Clearly information regarding IMD (implantable medical device)

operation would suggest the inclusion of stimulation parameters to anyone of ordinary skill in the art concerned with researching implant operation and treatment effectiveness. Ignorance of stimulation parameters when reprogramming, updating, researching, optimizing, or adjusting the IMD would certainly be detrimental to the patient under treatment and quite possibly subject the medical practitioner to a malpractice suit. Interaction between parameters may negatively affect the effectiveness of stimulation if one parameter is blindly adjusted without knowledge of its effect on other related parameters, the current values of those parameters, and the pre-adjustment level of the parameter of interest.

In summary, it is the examiner's position that a reasonable person of ordinary skill in the art given the explicit and implied teachings of Schulman et al., Novak et al., and Nelson et al., along with the logical reasoning proffered by the examiner, would clearly recognize the establishment of a valid *prima facie* case of obviousness. The appellant has generally mischaracterized the prior art, provided unsubstantiated allegations and unsupported conclusions, failed to distinguish the stimulation of any one particular peripheral nerve over the other, failed to distinguish the overall invention over the prior art of record, and has ultimately failed to meet the burden of credibly rebutting the *prima facie* case of obviousness presented above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Kennedy J. Schaetzle

Conferees:

Janet Baxter

Carl Layno